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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,211	11/21/2001	Timothy E. Benson	6241.N DV1	4477

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EXAMINER

STEADMAN, DAVID J

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,211

Applicant(s)

BENSON, TIMOTHY E.

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 21-43 and 54-69 is/are pending in the application.
4a) Of the above claim(s) 21-43 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6 and 54-69 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 21 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/1/05.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

- [1]** Claims 1-6, 21-43, and 54-69 are pending in the application.
- [2]** Applicants' amendment to the claims, filed 3/1/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3]** Applicants' amendment to the specification, filed 3/1/2005, is acknowledged.
- [4]** Applicants' amendment to Figure 12, filed 3/1/2005, is acknowledged.
- [5]** Receipt of an information disclosure statement, filed 3/1/2005, is acknowledged.
- [6]** Applicants' arguments filed 3/1/2005 have been fully considered and are deemed to be persuasive to overcome at least one of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [7]** The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

Election/Restriction

- [8]** Claims 21-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **with** traverse in the reply filed on 7/30/2004.
- [9]** Claims 1-6 and 54-69 are being examined on the merits.

Information Disclosure Statement

[10] The reference(s) cited in the information disclosure statement (IDS), filed 3/1/2005, has been considered by the examiner. A copy of Form PTO-1449 is attached to the instant Office action.

Drawings

[11] The objection to Figures 4 and 12 as not corresponding to the descriptions of Figures 4 and 12 in the specification is maintained for the reasons of record (§ [12] of the Office action mailed 10/1/2004) and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the first sheet of Figure 4 or 12 is "a conventional method for clarifying that the listing is intended to be a continuous listing, with the pages read consecutively."

Applicants' argument is not found persuasive. Regarding drawings that are intended as being a "continuous listing," 37 CFR 1.84(u)(1) states, "[p]artial views intended to form one complete view, on one or several sheets, must be identified by the same number followed by a capital letter," e.g., Figure 1A, Figure 1B, Figure 1C, etc. In this case, the multiple views of Figures 4 and 12 have not been so identified. Instead, the drawings of Figures 4 and 12 have been identified as, e.g., Figure 4A-1, Figure 4A-2, etc. If Figures 4 and 12 were identified in accordance with 37 CFR 1.84(u)(1), a skilled artisan would recognize that the multiple views are intended to form one complete view without need for a figure page to clarify the listing.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings

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will not be held in abeyance. If applicants maintain that the first sheet of Figures 4 and 12 is conventional, applicants are requested to direct the examiner's attention to the section(s) of MPEP that pertain to such a conventional method.

Specification/Informalities

[12] The objection to the specification for incorporating subject matter into this application by reference to a hyperlink embedded in the specification (§ [13] of the Office action mailed 10/1/2004) is withdrawn in view of the amendment to the specification.

[13] Upon further review of the specification, the examiner notes a paragraph at p. 16, lines 17-19 of the specification that does not appear to be related to the instant invention. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

[14] Applicants note the examiner listed claims 1-6 and 51-55 as being rejected under 35 U.S.C. 112, second paragraph, in the Office action mailed 10/1/2004. Because the examiner rejected claims 1-7 and 54-61 in the body of the rejection, applicants have interpreted the rejection as being directed to claims 1-7 and 54-61. Applicants' interpretation is correct. The examiner notes that the rejection should have listed claims 1-7 and 54-61. The listing of claims 1-6 and 51-55 was an editing error.

[15] Upon further consideration, the rejection of claims 1-6, 55-57, and 59-61 as being indefinite (§ [14] part [a] of the Office action mailed 10/1/2004) is withdrawn. The claims

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require that the claimed polypeptide comprise "at least a portion," e.g., a single amino acid, "of an S. aureus MurB or MurB-like" FAD or substrate binding pocket, wherein the FAD or substrate binding pocket is listed in Tables 1-3 and 4-6. The examiner agrees that, as written, the claims do not require a reference amino acid sequence for the amino acids of Table 1 in order to be definite.

[16] The rejection of claims 55-57 and 59-61 as being confusing (§ [14] part [d] of the Office action mailed 10/1/2004) is withdrawn in view of the amendment to the claims.

Claim Rejections - 35 USC § 101

[17] The rejection of claim(s) 1-7 and 54-61 under 35 U.S.C. 101 as being directed to non-statutory subject matter (§ [15] of the Office action mailed 10/1/2004) is withdrawn in view of the amendment to the claims. Specifically, the claimed polypeptide has been limited to those that are "purified," thus indicating the hand of the inventor.

Claim Rejections - 35 USC § 112, First Paragraph

[18] The new matter rejection of claim(s) 54-61 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (§ [16] of the Office action mailed 10/1/2004) and the reasons stated below.

RESPONSE TO ARGUMENT: Addressing claim 54, applicants argue the claim is directed to fragments of SEQ ID NO:1 that include amino acids of the FAD binding pocket as listed in Tables 1-3. Applicants argue the amino acid numbering of the range

of amino acids as recited in claim 54 is supported by the disclosure of the numbered residues in Tables 1-3.

Applicants' argument is not found persuasive. The amino acid residues disclosed in Tables 1-3 are not "a contiguous stretch of amino acids" as recited in the claim. For example, there is a 34 amino acid gap between the lowest numbered amino acid of Table 1, i.e., "TYR 42," and the second lowest numbered amino acid of Table 1, i.e., "TYR 77." As such, applicants have failed to demonstrate support for the recited range of amino acids as recited in the claim.

Addressing claim 58, applicants argue the claim is directed to fragments of SEQ ID NO:1 that include amino acids of the substrate binding pocket as listed in Tables 4-6. Applicants argue the amino acid numbering of the range of amino acids as recited in claim 58 is supported by the disclosure of the numbered residues in Tables 4-6.

Applicants' argument is not found persuasive. See the reasoning given above regarding claim 54.

[19] Claim(s) 62-65 and 67-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection and is necessitated by amendment.

Claim 62 is drawn to a purified polypeptide consisting of amino acids 14-229 of SEQ ID NO:1. Claims 63-65 and 67-69 limit the 3-D configuration of the polypeptide of claim 62 or 66, respectively.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description".

Regarding claim 62, as support for the recited range of amino acids, applicants state, "...the end points of the polypeptide recited in claim 62 are supported by...page 16, lines 23-24,... line 29,...and line 31." However, the examiner can find no support for a polypeptide consisting of a range of amino acids starting at position 14 and ending at position 229 of SEQ ID NO:1 at p. 16, lines 23-24, 29, and 31 of the specification. While applicants' cited support discloses the range of amino acids 42-98 and the range of amino acids 101-229, there is no support for a contiguous range of amino acids starting at position 42 and ending at position 229. Even assuming arguendo the specification provided support for the recited range of amino acids, the specification fails to provide support for claims 63-65.

Regarding claim 66, as support for the recited range of amino acids, applicants state, "[t]he end points of the polypeptide recited in new claim 66 are supported [at] page 16, line 24...and page 16, line 33 to page 17, line 1." The examiner acknowledges support for the range of amino acids 230-316 of SEQ ID NO:1 and further acknowledges support for a polypeptide consisting of this range of amino acids. However, the examiner can find no support for a polypeptide consisting of amino acids 230-316 of SEQ ID NO:1 and having a 3-D configuration defined by claims 67-69.

Applicants are invited to direct the examiner's attention to supporting disclosure for the limitations recited in claims 62-65 and 67-69.

[20] The written description rejection of claim(s) 1-6 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (§ [16] of the Office action mailed 10/1/2004) and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the genus of claimed polypeptides is described in the specification by more than a single representative species. Applicants argue the polypeptide includes a portion of an S. aureus MurB or MurB-like FAD binding pocket or an S. aureus MurB or MurB-like substrate binding pocket, which is described in the specification by identifying characteristics, including structure. Applicants further argue the specification provides guidance for a skilled artisan to determine suitable homology to SEQ ID NO:1.

Applicants' argument is not found persuasive. The examiner maintains the position that the single disclosed representative species, i.e., SEQ ID NO:1, fails to describe all members of the claimed genus. A "portion S. aureus MurB or MurB-like" FAD binding pocket or substrate binding pocket can be even a single amino acid of the recited binding pocket. As such, the members of the genus are widely variant, as the genus encompasses a polypeptide – having any sequence of amino acids and having any function – that comprises "at least a portion," e.g., a single amino acid, "of an S. aureus MurB or MurB-like" FAD or substrate binding pocket, wherein the FAD or substrate binding pocket is listed in Tables 1-3 and 4-6. MPEP § 2163 states, "[f]or inventions in an unpredictable art, adequate written description of a genus which

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embraces widely variant species cannot be achieved by disclosing only one species within the genus." Consequently, the single disclosed species of SEQ ID NO:1 fails to describe all members of the genus.

[21] The scope of enablement rejection of claims 1-6 and 54-69 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (§ [17] of the Office action mailed 10/1/2004) and for the reasons stated below.

RESPONSE TO ARGUMENT: Regarding claims 54-61, applicants argue the claims have been amended to recite polypeptides consisting of contiguous stretches of amino acids of SEQ ID NO:1 with defined starting and ending points.

Applicants' argument is not found persuasive. 35 U.S.C. 112, first paragraph, requires that the specification describe how to make and how to use the invention. In this case, the examiner acknowledges that a skilled artisan could make the polypeptides of claims 54-69 using recombinant techniques or synthetic techniques without undue experimentation. However, it is unclear to the examiner as to how a skilled artisan is to use the claimed polypeptides in accordance with the disclosure, which teaches the use of the claimed polypeptides as follows: "[t]his invention relates to the crystallization and structure determination of... S. aureus MurB" (p. 1, lines 14-16) in order to develop novel antibiotics against S. aureus using the 3-D structure thereof. Thus, applicants may argue that a skilled artisan can use the claimed fragments for crystallization and structure determination. However, in order to determine the structure of these fragments, one must first crystallize these fragments and it is highly unpredictable as to

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whether the crystallization conditions for the polypeptide of SEQ ID NO:1 will be applicable to the recited fragments of SEQ ID NO:1 of claims 54-61.

Even assuming arguendo one is successful in achieving diffraction-quality crystals of the recited fragments, there is no way to predict a priori whether the fragments would crystallize in a biologically relevant conformation and it is highly unpredictable as to whether the structure determined from these crystals is useful in designing antibiotics that bind to SEQ ID NO:1. In other words, the fragments may crystallize in a conformation that is very different from that of full-length SEQ ID NO:1 and thus it is highly unpredictable as to whether these fragments would be so useful in the design of anti-bacterial agents.

Regarding claims 1-6, applicants argue the specification enables the full scope of the claims, teaching how a skilled artisan how to make and use all polypeptides encompassed by the claims. Applicants argue the examiner has “not provided any reason to doubt the objective truth of the disclosure.”

Applicants' argument is not found persuasive. As noted above, 35 U.S.C. 112, first paragraph, requires that the specification describe how to make and how to use the invention. In this case, “the invention,” i.e., the claimed polypeptides, encompasses all polypeptides – having any sequence of amino acids and having any function – that comprise “at least a portion,” e.g., a single amino acid, “of an S. aureus MurB or MurB-like” FAD or substrate binding pocket, wherein the FAD or substrate binding pocket is listed in Tables 1-3 and 4-6. The invention encompasses all polypeptides that have been isolated, have yet to be isolated, and mutants and variants of all of these

polypeptides. Also as noted above, the specification discloses that "[t]his invention relates to the crystallization and structure determination of...S. aureus MurB" (p. 1, lines 14-16). In this case, undue experimentation is clearly required to make all polypeptides, including polypeptides that have yet to be isolated, and how to use all polypeptides, particularly how to crystallize all polypeptides for structural determination. In this case, the specification is enabling only for the polypeptide of SEQ ID NO:1.

Claim Rejections - 35 USC § 102

[22] The rejection of claim(s) 1-6 under 35 U.S.C. 102(e) as being anticipated by Wallis et al. (US Patent 6,225,098 B1) and the rejection of claim(s) 1-6 under 35 U.S.C. 102(b) as being anticipated by Database GenBank Accession Number P08373 are maintained for the reasons of record (¶¶ [19] and [20] of the Office action mailed 10/1/2004) and for the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue neither of the cited documents or the underlying documents of Database GenBank Accession Number P08373 discloses 3-D structural information as recited in claims 1-6.

Applicants' argument is not found persuasive. There is no requirement that the claimed polypeptides exhibit the 3-D structural characteristic(s) as recited in the claims. The only requirement is that the claimed polypeptide comprise "at least a portion of an S. aureus MurB or MurB-like" FAD binding pocket or substrate binding pocket, wherein the FAD or substrate binding pocket is listed in Tables 1-3 and 4-6. In this case, a portion can be a single amino acid and the polypeptides as disclosed by the cited

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references comprise such a "portion" of the FAD binding pocket of Tables 1-3 or the substrate binding pocket of Tables 4-6.

[23] The rejection of claim(s) 54-61 under 35 U.S.C. 102(b) as being anticipated by Sigma Chemical Catalog 1993 is withdrawn in view of the amendment to the claims.

Conclusion

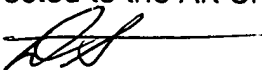
[24] Status of the claims:

- Claims 1-6, 21-43, and 54-69 are pending.
- Claims 21-43 are withdrawn from further consideration.
- Claims 1-6 and 54-69 are rejected.
- No claim is in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 6:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.


DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER